



11-25-05

AF/2873 JEFW

TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.
353/100

Re Application Of:

STEPHEN LEROY POLLARD

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/388,069	9/1/1999	HUNG X DANG	NONE	2873	3357

Invention:
COMFORT OPTICS VISOR

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:
OCTOBER 12, 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: \$250.00

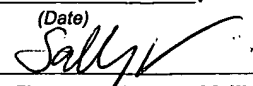
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Dated: NOVEMBER 22, 2005

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353-100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Group Art Unit: 2873
STEPHEN LEROY POLLARD)	Examining Attorney: Hung X Dang
Serial No.: 09/388,069)	Pasadena, California
Filed: September 1, 1999)	Date: November 22, 2005
For: COMFORT OPTICS VISOR)	

APPEAL BRIEF

This Appeal Brief is submitted pursuant to 37 CFR 1.192. This is an appeal from the FINAL REJECTION dated April 14, 2005.

1. Real Party In Interest

The party named in the caption is the real party in interest. Mr. Pollard has not assigned his interest.

2. Related Appeals and Interferences

There are no related appeals or interferences involving Mr. Pollard and/or this patent application.

3. Status of Claims

Claims 7 to 9, inclusive are pending and are appealed. Claims 1 to 6 have been canceled.

4. Status of Amendments

There were no amendments filed subsequent to the Final Rejection appealed from, dated April 14, 2005. We did receive a "Notice of Non-Compliant Amendment" subsequent to the issuance of the Final Rejection to which we responded to the satisfaction of the Examiner. However, this exchange had no effect on claims 7 to 9 which stand as they were at the time of the issuance of the Final Rejection.

5. Summary of Invention

The invention is best understood by first considering the problem which it addresses.

Frequently, the visually impaired are provided with monoculars. Monoculars, called biopic glasses, provide only a degree of tunnel vision due to lack of adjustability in relation to the eyes when incorporated in a conventional pair of eyeglasses.

The present invention provides a novel visor for carrying a pair of monoculars wherein the position of each of the monoculars can be adjusted laterally (side to side) and vertically (up and down) by the patient to enable the patient to optimize the benefits of the monoculars in the enhancement of vision.

6. Issues

The issues on appeal are as follows¹:

1. Whether claims 7 to 9 are properly rejected as containing “new matter” under 35 USC 132.

2. Whether claims 7 to 9 are properly rejected as failing to comply with the written description requirements of 35 USC 112.

3. Whether claims 7 to 9 are properly rejected under 35 USC 103(a) as being obvious to one of ordinary skill in the relevant art at the making of the invention in view of Chang et al. United States Patent No. 5,920,371 in view of Leonardi et al. United States Patent No. 5,642,178.

¹ It is unclear what issues remain. Appellant is briefing all issues raised in the Final Rejection of April 14, 2005. It may be that the Examiner withdrew some of these issues by the cryptic Advisory Office Action issued November 1, 2005, further discussed hereinbelow.

For convenience, we have attached the Chang et al. and Leonardi et al. citations to this Appeal Brief.

The Appendix hereto contains a true copy of the claims on appeal.

7. Grouping of Claims

Claims 7 through 9 are to be considered individually.

8. Argument

In paragraphs 2,3 and 5 of the Final Rejection the Examiner objected to alleged “new matter” under 35 U.S.C. 132 (Paragraph 2); to the same “new matter” as the sole apparent basis for the rejection under 35 U.S.C. 112, first paragraph (Paragraph 3); and as the reason for the rejection on Chang et al. United States Patent No. 5,920,371 in view of Leonardi et al. United States Patent No. 5,642,178 under 35 U.S.C. 103(a), as maintained in Paragraph 4 and as subsequently set forth in Paragraph 5.

1. The Rejection On New Matter (35 USC 132)²

The rejections should be reversed because there is no new matter.

The “new matter” is alleged to be in the words “integrally attached side bands extending outward from at each side of said expansion loop at its upper end at said split and terminating in a free distal end”.

Specifically, the Examiner stated in the Final Rejection:

“The original disclosure does not support for ‘integrally attached side bands extending outward from at each side of said expansion loop, each side band being attached to said expansion loop at its upper end at said split and terminating in a free distal end.’ as recited in claim 7.

“Applicant is required to cancel the new matter in the reply to this Office Action.”

² Insofar as the record reveals, this rejection as advanced by the Examiner was applicable only to claim 7.

We attach herewith as Attachment A, Figures 1 to 3 of the drawings on file together with the elements of claim 7 shown thereon. There is no new matter. The side band structure of claim 7 is precisely as shown in these Figures. See Attachment B which is claim 7 as read on the drawings.

While the Examiner never makes clear the reason for the rejection, it appears to stem from a failure to treat the drawings as well as the Specification as providing the "written description" taken as a whole.

On this issue, the present case is similar to several of the cases discussed in Vas-Cath Inc. v. Mahurkar, 19 USPQ 2d 1111 (Fed. Cir. 1991). For convenience a copy of this discussion is attached as Attachment C. See Vas-Cath at pp. 1117-1118. Also, Pandrol USA, Inc. v. Airboss Ry. Products, 424 F.3d 1161, 1165 (CAFC 2005).

The rejection for "new matter" should be reversed.

2. The Rejection Under 35 USC 112, First Paragraph³

The Examiner apparently argues that there is inadequate written description

³ There is nothing in the record to suggest, except for the dependency of claims 8 and 9 from claim 7, how this rejection was intended by the Examiner to apply other than to claim 7.

without taking into account the drawings. In the Final Rejection, the Examiner stated:

“Claims 7-9 are rejected under 35 U.S.C. 112, the first paragraph, as failing to comply with the written description requirement. The claims(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not described [sic] the claimed invention as recited in new claims 7-9.”

We have discussed the drawings hereinabove. When the drawings and the Specification are taken as one, the requirements of a written description are fully satisfied, see Vas-Cath Inc. and Pandrol USA, Inc., both supra.

The rejection under 35 USC 112, first paragraph, should be reversed.

3. The Rejection On Chang et al. and Leonardi et al. (35 USC 103)

Chang et al. discloses an optical mounting assembly utilizing a headband mount having a forward portion and a vertical member having upper and lower ends. The forward portion of the headband mount includes a slide assembly which receives the upper end of the vertical member, allowing the vertical member to be vertically adjusted

and locked into place once a desired position is achieved. A clamp assembly is provided to connect the lower end of the vertical member to the top edge of the eyeglass frames. In Chang et al. the ocular mounting assembly has a slide rail centrally attached to eyeglass frames at a point proximate to where the clamp assembly connects the lower end of the vertical member to the top edge of the eyeglass frames. A mounting pad is received by the slide rail which may be vertically adjusted and locked into place once a desired orientation is achieved, and a clamp assembly is used to connect the mounting pad to the ocular mounting assembly.

Leonardi relates to a pair of sports eyeglasses having a substantially hard, rigid frame, a pair of soft, resilient strap connector pads, and a headband assembly coupled to the rigid frame by the soft resilient strap connector pads. The headband assembly includes a first elastic strap extending between the soft, resilient connector pads, a second strap coupled at its ends to the first strap and extending over the top of the user's head, and a third strap extending between the first and second straps along a rear portion of the wearer's head.

Neither Chang et al. or Leonardi disclose or suggest as per claim 7 side bands in conjunction with the expansion loop over the top of the head to allow the wearer to easily manually adjust. Further, the cited prior art does not disclose or suggest the structure recited in claims 8 and 9.

In an Advisory Office Action dated November 1, 2005, the Examiner stated:

“Applicant argued that ‘Neither Chang et al or Leonardi disclose or suggest as per claim 7 side bands in conjunction with the expansion loop over the top of the head to allow the wearer to easily manually adjust.’

“In response to applicant’s argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., side bands in conjunction with the expansion loop over the top of the head to allow the wearer to easily manually adjust) are not recited in the rejected claims(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).”

Claim 7 does, of course, affirmatively recite the side bands and the expansion loop adapted to run over the top of the head. The claimed structure is not described or suggested by the cited prior art. The functional advantages of the claimed structure are not required to be recited in the body of the claims. *In re Van Guens*, *supra.*, refers to the familiar rule that “limitations are not to be read into the claims from the Specification.” We do not rely on any such limitations and the Examiner has not identified any such limitations.

The rejection on prior art should be reversed. As the Examiner appears, at least tacitly, to acknowledge, the Chang et al. and Leonardi et al. patents do not render obvious all of the elements that make up the structure of claim 7. Thus, even when combined, Chang et al. and Leonardi do not point to the subject matter of claim 7.

The record is devoid of any explanation of a justification for combining Chang et al. with Leonardi et al.

As to claims 8 and 9, the Examiner never has advanced a coherent explanation of how Chang et al. plus Leonardi et al. leads to the subject matter of either claim 8 or claim 9.

Claims 7, 8 and 9 are allowable over the cited prior art and the rejection on Chang et al. and Leonardi et al. should be reversed.

It is axiomatic that the prior art itself must provide an incentive to combine references, see, e.g., In re Sernaker, 217 USPQ 1 (Fed. Cir. 1983), ACS Hospital Systems, Inc. v. Montefiore Hospital, 221 USPQ 929, 933 (Fed. Cir. 1984), In re Oetiker, 16 USPQ2D 1926 (Fed. Cir. 1992), In re Dembiczak, 50 USPQ2D 1614 (Fed. Cir. 1999).

The proper legal approach has been recently summarized in In re Kumar, 76 USPQ 2d 1048, 418 F.3d 1361 (Fed. Cir. 2005) at pages 1365-68:

“Determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying facts. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 S.Ct 684, 15 L.Ed.2d 545 (1966); *In re Oetiker*, 977 F.2d 1443, 1444 (Fed.Cir.1992); *In re Piasecki*, 745 F.2d 1468, 1471 (Fed.Cir.1984). We give plenary review to the Board’s legal conclusion, whereas the underlying factual determinations are reviewed to ascertain whether they are supported by substantial evidence. *In re Gartside*, 203 F.3d 1305, 1316 (Fed.Cir.2000). Substantial evidence is ‘such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.’ *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229, 59 S.Ct 206, 83 L.Ed.2d 126 (1938).

“During examination, the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *Oetiker*, 977 F.2d at 1445. The *prima facie* case is a procedural tool, and requires that the examiner initially produce evidence sufficient to support a ruling of obviousness; thereafter the burden shifts to the applicant to come forward with evidence or

argument in rebuttal. *Piasecki*, 745 F.2d at 1475.⁴ When rebuttal evidence is provided, the *prima facie* case dissolves, and the decision is made on the entirety of the evidence. *Oetiker*, 977 F.2d at 1445; *In re Spada*, 911 F.2d 705, 708 (Fed.Cir.1990); *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976)....

“An applicant may rebut a *prima facie* case of obviousness by providing a ‘showing of facts supporting the opposite conclusion.’ Such a showing dissipates the *prima facie* holding and requires the examiner to ‘consider all of the evidence anew.’ *Piasecki*, 745 F.2d at 1472; *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976). Rebuttal evidence may show, for example, that the claimed invention achieved unexpected results relative to the prior art, *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed.Cir.1997); that the prior art teaches away from the claimed invention, *id* at 1471; that objective evidence (e.g., commercial success) supports the conclusion that the invention would not have been obvious to a skilled artisan, *Piasecki*, 745 F.2d at 1475; or that the prior art did not enable one skilled in the art to produce the now-claimed invention, *In re Payne*, 606 F.2d 303, 314-15 (CCPA 1979).” [emphasis added]

⁴ We submit that no *prima facie* case of obviousness has been made out. Further, even if such were to be found, it is effectively rebutted by the Declaration of Stephen LeRoy Pollard Under 37 CFR 1.132, on file.

It is axiomatic that the prior art itself must suggest the desirability of the claimed invention.

“There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art.” In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2D 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a prima facie case of obvious was held improper.) The level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2D 1161 (Fed. Cir. 1999).

“In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.” In re Linter, 458 F.2d 1013, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an

implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2D 1313, 1317 (Fed. Cir. 2000). See also In re Fine, 837 F.2d 1071, 5 USPQ2D 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2D 1941 (Fed. Cir. 1992).

In In re Kotzab, the claims were drawn to an injection molding method using a single temperature sensor to control a plurality of flow control valves. The primary reference disclosed a multizone device having multiple sensors, each of which controlled an associated flow control valve, and also taught that one system may be used to control a number of valves. The court found that there was insufficient evidence to show that one system was the same as one sensor. While the control of multiple valves by a single sensor rather than by multiple sensors was a “technologically simple concept,” there was no finding “as to the specific understanding or principle within the knowledge of the skilled artisan” that would have provided the motivation to use a single sensor as the system to control more than one valve. 217 F.3d at 1371, 55 USPQ2D at 1318.

In In re Fine, the claims were directed to a system for detecting and measuring minute quantities on nitrogen compounds comprising a gas chromatograph, a converter which converts nitrogen compounds into nitric oxide by combustion, and a nitric oxide detector. The primary reference disclosed a system for monitoring sulfur compounds

comprising a chromatograph, combustion means, and a detector, and the secondary reference taught nitric oxide detectors. The examiner and Board asserted that it would have been within the skill of the art to substitute one type of detector for another in the system of the primary reference, however the court found there was no support or explanation of this conclusion and reversed.

In In re Jones, the claimed invention was the 2-(2 ϕ aminoethoxy) ethanol salt of dicamba, a compound with herbicidal activity. The primary reference disclosed inter alia the substituted ammonium salts of dicamba as herbicides, however the reference did not specifically teach the claimed salt. Secondary references teaching the amine portion of the salt were directed to shampoo additives and a byproduct of the production of morpholine. The court found there was no suggestion to combine these references to arrive at the claimed invention.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2D 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber

and is entrained in the ingredients during operation. Although a prior art device “may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.” 916 F.2d at 682, 16 USPQ2D at 1432.) See also In re Fritch, 972 F.2d 1260, 23 USPQ2D 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references.)

The fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish prima facie obviousness.

A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teaching that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levengood, 28 USPQ2D 1300 (Bd. Pat. App. & Inter. 1993). See also In re Kotzab, 217 F.3d 1365, 55 USPQ2D 1313, 1318 (Fed. Cir. 2000) (Court reversed obviousness rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention); Al-Site Corp. v. VSI Int’l Inc., 174 F.3d 1308, 50 USPQ2D 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the

suggestion to combine references.)

This rejection should be reversed.

CONCLUSION

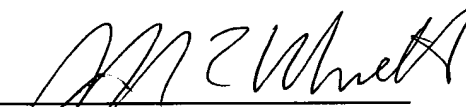
The primary reference, Chang et al., is not properly combinable with the secondary reference Leonardi et al. in a manner consistent with the law under 35 USC 103(a).

Even if combined, the combinations of references do not render obvious the instant invention to one of ordinary skill in the art. The cited prior art actually teaches away from the present invention and actually provides convincing evidence of the non-obviousness of the present invention.

The FINAL Rejection should be reversed.

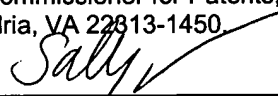
Dated: November 22, 2005

Respectfully submitted,

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Alexandria, VA 22313-1450.



SALLY SHORE

Date: November 22, 2005

APPENDIXPENDING CLAIMS IN U.S. PATENT APPLICATIONSERIAL NO. 09/388,069

Claim 7. A headband comprising an expansion loop adapted to run from one side of the head over the top of the head to the other side of the head, the expansion loop being split at each side of head

a back loop adapted to run around the back of the head

a front loop adapted to run from one side of the head across the wearers forehead to the other side of the head

integrally attached side bands extending outward from at each side of said expansion loop, each side band being attached to said expansion loop at its upper end at said split and terminating in a free distal end.

Claim 8. The headband of claim 7 further comprising a visor having a front piece adapted to be positioned in front of the wearer's eyes, and side pieces each of which extend from the front piece to the free distal end of said side band, and being rotatably attached to said band, said front piece carrying at its center an upwardly projecting slotted member, said front loop of said headband further having a fastening means which adjustably engages with said slot member so that the visor may be rotated up or down to suit the wearer and then said fastening means being set to fix the up and down position of said visor.

Claim 9. The headband of claim 8 still further comprising said center piece of said visor having two spaced apart elongated mounting ports adapted to be positioned before the wearers eyes and each having received therein one viewing end of a monocular, said front piece carrying an alignment adjustment support

said alignment adjustment support comprising:

- (i) two outwardly extending projections above and at each side of each monocular,
- (ii) a threaded member carried at each of its ends above each monocular by said outwardly extending projections,
- (iii) threadably movable on and carried by each said threaded member a means for engaging the exterior surface of said monocular so that when said threaded member is rotated, said monocular is laterally moved within said elongated mounting port.



Figure 1

Top View of Headband

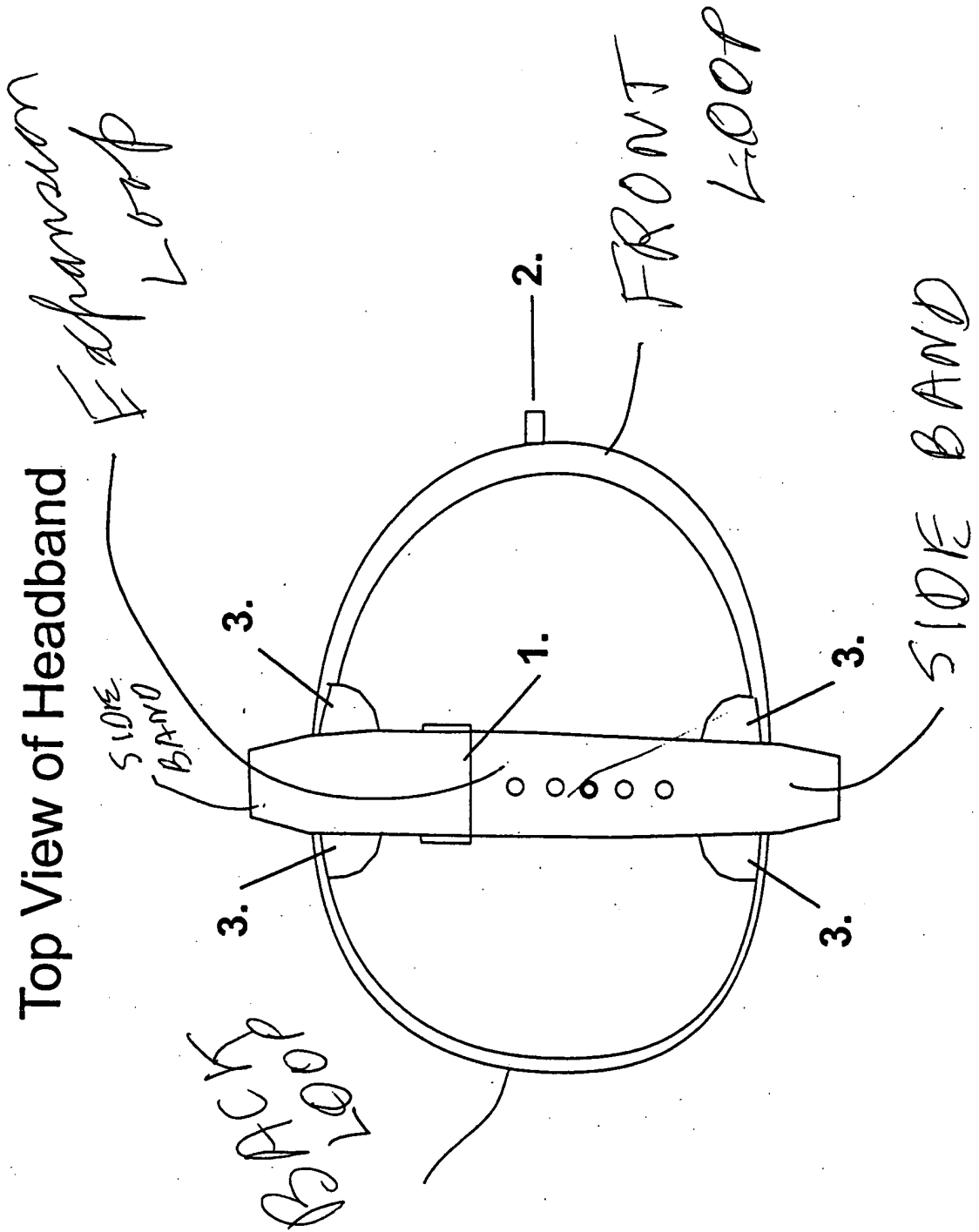




Figure 2

Front View of Headband

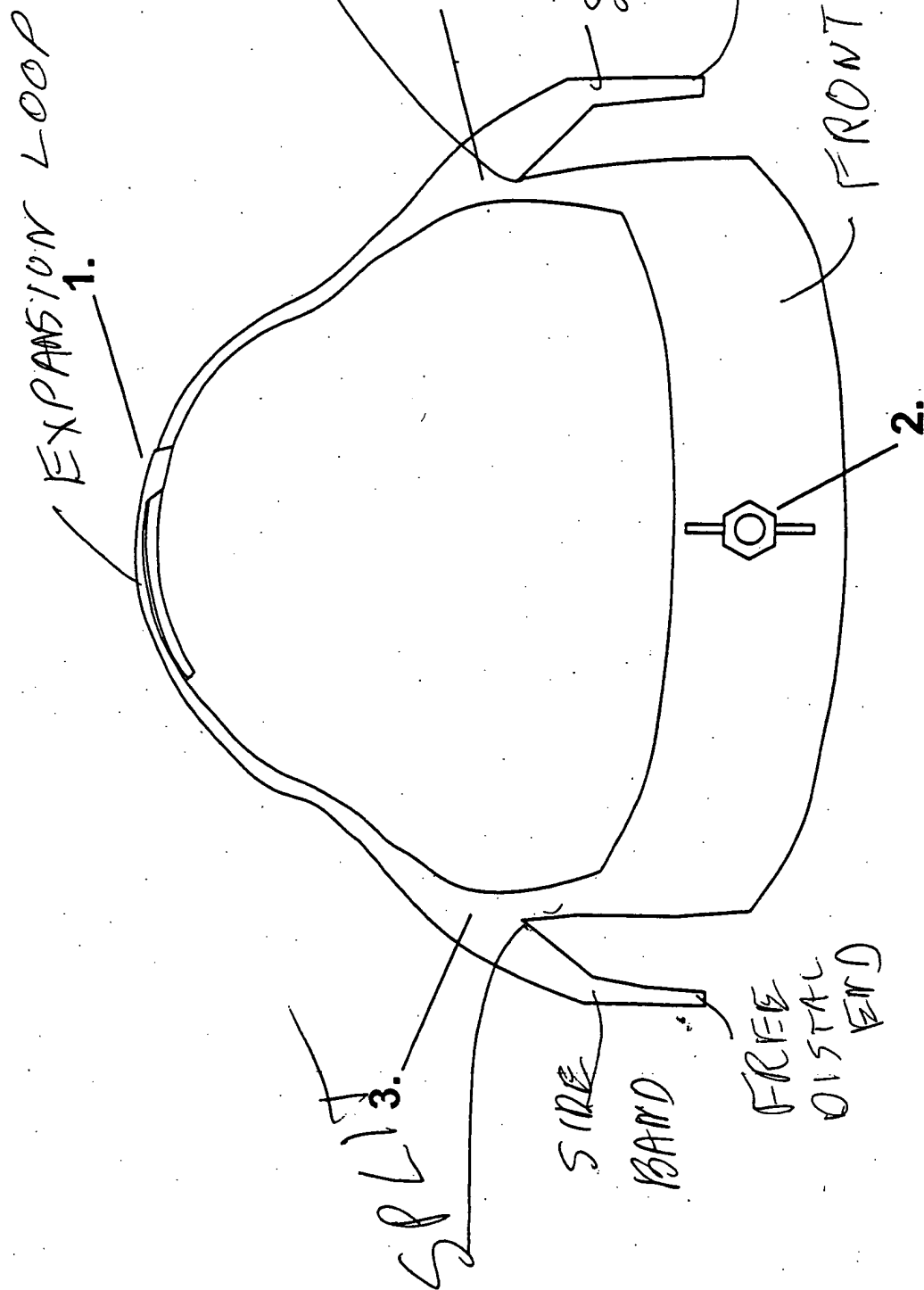
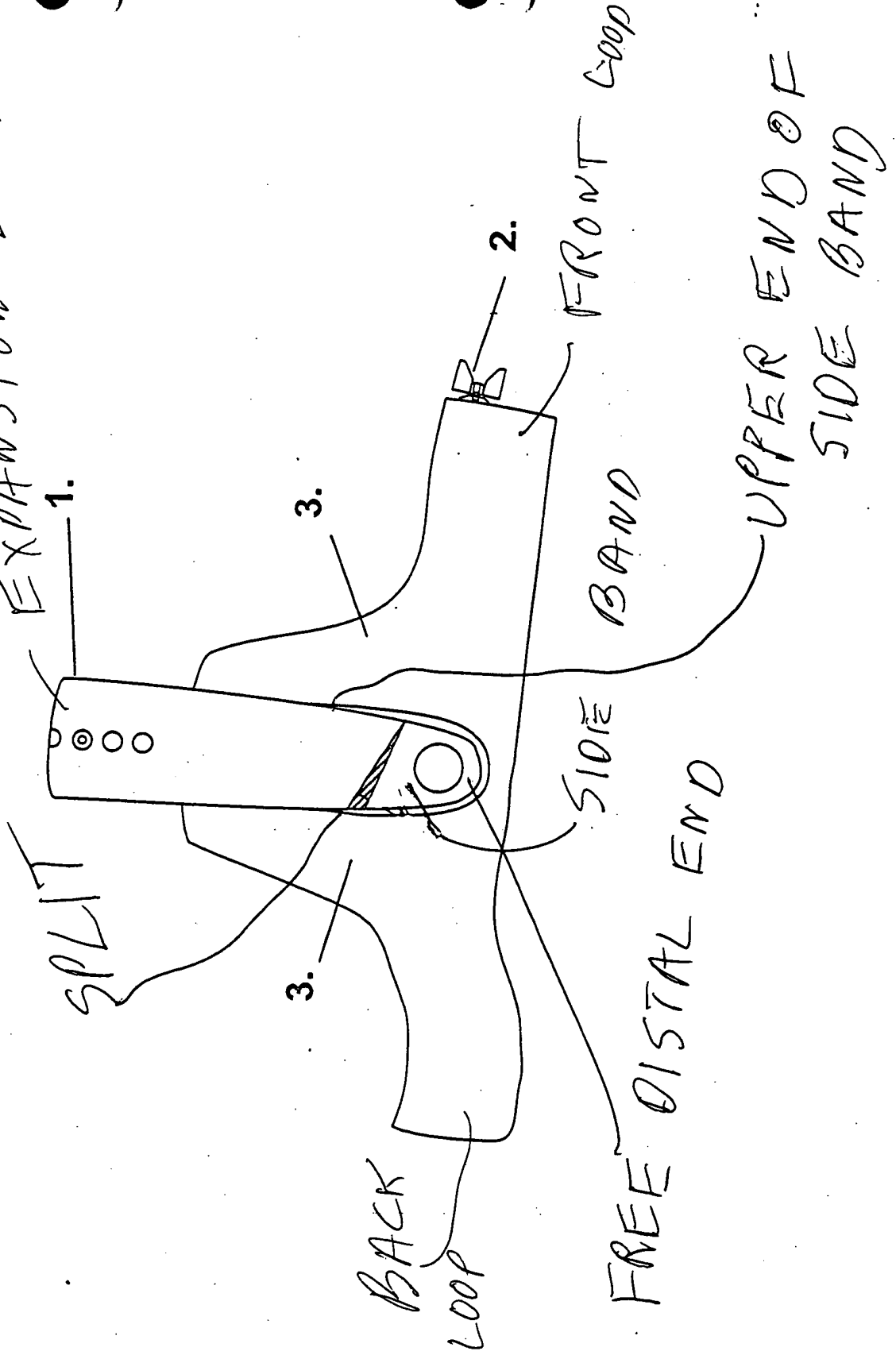


Figure 3

Side View of Headband

EXPANSION LOOP





09/388,069

Attorney Docket No. 353-100

ATTACHMENT B

Claim 7 (New) A headband comprising an expansion loop adapted to run from one side of the head over the top of the head to the other side of the head, the expansion loop being split at each side of head

a back loop adapted to run around the back of the head

a front loop adapted to run from one side of the head across the wearers forehead to the other side of the head

integrally attached side bands extending outward (see Figure 2) from at each side of said expansion loop, each side band being attached to said expansion loop at its upper end (see Figure 3) at said split (see Figures 2 and 3) and terminating in a free distal end (see Figure 2).

19 USPQ2d

any proven

he proven harm both the striking to the Dove and is are advertised a general matter the degree of d on LTS expected status of its s inadequate to falls short of an inst importation ts current form. TS has not affir- rower remedies he serious pros- fusion about onorship of the

cers, agents and cting in concert nts and employ- the pendency of or causing to be states, and from moting, or caus- promoted in the entified by LTS TS-614 and the

on of whether the ciently broad to of the same lamp infringe the trade the prior history Dove trade dress, uted and should the scope of the broadly worded r future infringe- f the Dove, e.g., *Elegra Inc.*, 690 ropriate. First, it tility in defining prohibited con- ve the undesired m continuing to g lamps that may products already the likelihood of court will instead , agents and em- g in concert with s and employees the pendency of ; or causing to be states, and from moting, or caus- promoted in the sk lamp incorpo- features of the

19 USPQ2d

Vas-Cath Inc. v. Mahurkar

1111

LTS-614, the LTS-619 or the Dove, without giving PAF, by its counsel, two weeks written notice before any importation, distribution, sale or promotion, with such notice to include a clear photograph of the new lamp as seen in profile, from the front and from the rear.

PAF is directed to settle an appropriate order within three (3) days embodying the foregoing terms. LTS is to serve and file with the Court within the same time period, one or more affidavits addressing the appropriate amount, if any, of a bond.

SO ORDERED.

Court of Appeals, Federal Circuit

Vas-Cath Inc. v. Mahurkar

Nos. 90-1528, 91-1032

Decided June 7, 1991

JUDICIAL PRACTICE AND PROCEDURE

1. Procedure — Summary judgment — In general (§410.3301)

Procedure — Judicial review — Standard of review — In general (§410.4607.01)

Court of appeals, in reviewing grant of summary judgment, is not bound by federal district court's holding that no material facts are in dispute, and must make independent determination as to whether standards for summary judgment have been met.

PATENTS

2. Patentability/Validity — Specification — Written description (§115.1103)

"Written description" of invention required by first paragraph of 35 USC 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed.

3. Practice and procedure in Patent and Trademark Office — Prosecution — Drawings (§110.0920)

Patentability/Validity — Specification — Written description (§115.1103)

Drawings alone may, under proper circumstances, provide "written description" of

invention required by 35 USC 112, and whether drawings are from design application or utility application is not determinative.

4. Patentability/Validity — Specification — Written description (§115.1103)

Federal district court erred by requiring drawings from design patent application to "describe what is novel or important" about invention in order to satisfy "written description" requirement of 35 USC 112 for later-filed utility patent on double lumen catheter having combination of features, since there is no legally cognizable or protected "essential" element, "gist" or "heart" of invention in combination patent; rather, invention is defined by claims under consideration.

5. Patentability/Validity — Specification — Written description (§115.1103)

Federal district court erred by considering patents granted to applicant after utility patents containing claims in question in determining whether drawings from design application satisfy "written description" requirement of 35 USC 112 for those claims, since later patenting of inventions having different specifications is irrelevant to determination of Section 112 sufficiency of application in question, which must be judged as of its filing date.

6. Patentability/Validity — Specification — Written description (§115.1103)

Federal district court erred by imposing legal standard that essentially required drawings from design application for double lumen catheter to necessarily exclude all diameters of lumens, other than those within range specified by subsequently-filed utility claims, in order to satisfy "written description" requirement of 35 USC 112 for those claims, since proper test is whether drawings conveyed, with reasonable clarity to those of ordinary skill in art, that applicant had in fact invented catheter having return lumen of diameter within claimed range; defendant's submission of expert's declaration stating that person of ordinary skill viewing drawings would be able to derive claimed range therefrom, and plaintiff's failure to refute such declaration, therefore gave rise to genuine issue of material fact inappropriate for summary disposition.

Particular patents — General and mechanical — Catheters

4,568,329, Mahurkar, double lumen catheter, summary judgment of invalidity reversed.

4,692,141, Mahurkar, double lumen catheter, summary judgment of invalidity reversed.

Appeal from the U.S. District Court for the Northern District of Illinois, Easterbrook, J.; 17 USPQ2d 1353.

Action by Vas-Cath Inc. and Gambro Inc. against Sakham D. Mahurkar and Quinton Instruments Co., for declaratory judgment of patent non-infringement, in which defendants counterclaim for patent infringement. From entry of summary judgment holding patents invalid, defendants appeal. Reversed and remanded.

William L. Mentlik, of Lerner, David, Littenberg, Krumholz & Mentlik (Roy H. Wepner, John R. Nelson, and Joseph S. Littenberg, with him on brief), Westfield, N.J., for plaintiffs-appellees.

Raymond P. Niro, of Niro, Scavone, Haller & Niro, Chicago, Ill. (Joseph N. Hosteny and John C. Janka, with him on brief; Michael P. Mazza, of counsel); Michael J. Sweedler, of Darby & Darby, New York, N.Y., for defendants-appellants.

Before Rich, Michel, and Plager, circuit judges.

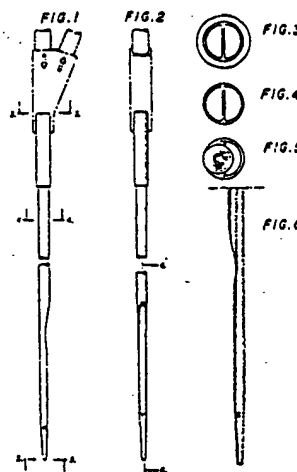
Rich, J.

Sakham D. Mahurkar and Quinton Instruments Company (collectively Mahurkar) appeal from the September 12, 1990 partial final judgment¹ of the United States District Court for the Northern District of Illinois, Easterbrook, J., sitting by designation, in Case No. 88 C 4997. Granting partial summary judgment to Vas-Cath Incorporated and its licensee Gambro, Inc. (collectively Vas-Cath), the district court declared Mahurkar's two United States utility patents Nos. 4,568,329 ('329 patent) and 4,692,141 ('141 patent), titled "Double Lumen Catheter," invalid as anticipated under 35 USC 102(b). In reaching its decision, reported at 745 F.Supp. 517, 17 USPQ2d 1353, the district court concluded that none of the twenty-one claims of the two utility patents was entitled, under 35 USC 120, to the benefit of the filing date of Mahurkar's earlier-filed United States design patent ap-

plication Serial No. 356,081 ('081 design application), which comprised the same drawings as the utility patents, because the design application did not provide a "written description of the invention" as required by 35 USC 112, first paragraph. We reverse the grant of summary judgment with respect to all claims.

BACKGROUND

Sakham Mahurkar filed the '081 design application, also titled "Double Lumen Catheter," on March 8, 1982. The application was abandoned on November 30, 1984. Figures 1-6 of the '081 design application are reproduced at right [below].



As shown, Mahurkar's catheter comprises a pair of tubes (lumens) designed to allow blood to be removed from an artery, processed in an apparatus that removes impurities, and returned close to the place of removal. Prior art catheters utilized concentric circular lumens, while Mahurkar's employs joined semi-circular tubes that come to a single tapered tip. Advantageously, the puncture area of Mahurkar's semicircular catheter is 42% less than that of a coaxial catheter carrying the same quantity of blood, and its conical tip yields low rates of injury to the blood. The prior art coaxial catheters are now obsolete; Mahurkar's catheters appear to represent more than half of the world's sales. 745 F.Supp. at 520, 17 USPQ2d at 1353-54.

After filing the '081 design application, Mahurkar also filed a Canadian Industrial Design application comprising the same

drawings plus additional. On August 9, 1984, Design 50,089 ('89) that application.

More than one 1984, Mahurkar patent application. the patents now utility application as the '081 No. 656,601 ('81) claimed the benefit of the '081 design application. A "continuous" Action mailed June 1984. Trademark Office that "the prior application," but did not. application was entered January 29, 1986, 823,592 ('92) claiming the benefit of the '081 design application. the '601 utility action mailed April 1986. stated that the '5 "considered to be" cant's parent application. March 8, 1982. tion]. The '601 issued in 1986 and '329 and '141 patent. The independent claims are set forth.

Vas-Cath sued Mahurkar seeking a declaratory judgment that its catheters did not infringe Mahurkar's '329 and '141 patents. Vas-Cath's complaint alleged that the '329 and '141 patents were anticipated by Canadian '089. Victory was premised on 35 USC 120 '4 to '1.

¹ The utility patents contain minor shading but no numerals not present in the drawings.

² Vas-Cath's appeal arose from a 1988 Circuit Court decision in Mahurkar for infringement.

³ Section 120, titled "Date in the United States,"

An application disclosed in the n paragraph of section application previous States, or as provided title, which is filed

¹ The district court directed entry of final judgment as to the issue of patent invalidity pursuant to Fed.R.Civ.P. 54(b).

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'081 design ble Lumen the applica- er 30, 1984. plication are

FIG. 3

FIG. 4

FIG. 5

FIG. 6

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drawings plus additional textual description. On August 9, 1982, Canadian Industrial Design 50,089 (Canadian '089) issued on that application.

More than one year later, on October 1, 1984, Mahurkar filed the first of two utility patent applications that would give rise to the patents now on appeal. Notably, both utility applications included the same drawings as the '081 design application.³ Serial No. 656,601 ('601 utility application) claimed the benefit of the filing date of the '081 design application, having been denominated a "continuation" thereof. In an Office Action mailed June 6, 1985, the Patent and Trademark Office (PTO) examiner noted that "the prior application is a design application," but did not dispute that the '601 application was entitled to its filing date. On January 29, 1986, Mahurkar filed Serial No. 823,592 ('592 utility application), again claiming the benefit of the filing date of the '081 design application (the '592 utility application was denominated a continuation of the '601 utility application). In an office action mailed April 1, 1987, the examiner stated that the '592 utility application was "considered to be fully supported by applicant's parent application SN 356,081 filed March 8, 1982 [the '081 design application]." The '601 and '592 utility applications issued in 1986 and 1987, respectively, as the '329 and '141 patents, the subjects of this appeal. The independent claims of both patents are set forth in the Appendix hereto.

Vas-Cath sued Mahurkar in June 1988, seeking a declaratory judgment that the catheters it manufactured did not infringe Mahurkar's '329 and '141 utility patents.⁴ Vas-Cath's complaint alleged, *inter alia*, that the '329 and '141 patents were both invalid as anticipated under 35 USC 102(b) by Canadian '089. Vas-Cath's anticipation theory was premised on the argument that the '329 and '141 patents were not entitled under 35 USC 120⁵ to the filing date of the '081

design application because its drawings did not provide an adequate "written description" of the claimed invention as required by 35 USC 112, first paragraph.

Mahurkar counterclaimed, alleging infringement. Both parties moved for summary judgment on certain issues, including validity. For purposes of the summary judgment motion, Mahurkar conceded that, if he could not antedate it, Canadian '089 would represent an enabling and thus anticipating §102(b) reference against the claims of his '329 and '141 utility patents. 745 F.Supp. at 521, 17 USPQ2d at 1355. Vas-Cath conceded that the '081 design drawings *enabled* one skilled in the art to practice the claimed invention within the meaning of 35 USC 112, first paragraph. *Id.* Thus, the question before the district court was whether the disclosure of the '081 design application, namely, the drawings without more, adequately meets the "written description" requirement also contained in §112, first paragraph, so as to entitle Mahurkar to the benefit of the 1982 filing date of the '081 design application for his two utility patents and thereby antedates Canadian '089.

Concluding that the drawings do not do so, and that therefore the utility patents are anticipated by Canadian '089, the district court held the '329 and '141 patents wholly invalid under 35 USC 102(b), *id.* at 524, 17 USPQ2d at 1358, and subsequently granted Mahurkar's motion for entry of a partial final judgment under Fed.R.Civ.P. 54(b) on the validity issue. This appeal followed.

DISCUSSION

The issue before us is whether the district court erred in concluding, on summary judgment, that the disclosure of the '081 design application does not provide a §112, first paragraph "written description" adequate to support each of the claims of the '329 and '141 patents. If the court so erred as to any of the 21 claims at issue, the admittedly anticipatory disclosure of Canadian '089 will have been antedated (and the basis for the court's

³ The utility patent drawings contain additional but minor shading and lead lines and reference numerals not present in the design application drawings.

⁴ Vas-Cath's apprehension of suit apparently arose from a 1988 Canadian action instituted by Mahurkar for infringement of Canadian '089.

⁵ Section 120, titled "Benefit of Earlier Filing Date in the United States," provides (emphasis ours):

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors

named in the previously filed application shall have the same effect as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

grant of summary judgment nullified) as to those claims.

[1] In reviewing the district court's grant of summary judgment, we are not bound by its holding that no material facts are in dispute, and must make an independent determination as to whether the standards for summary judgment have been met. *C.R. Bard, Inc. v. Advanced Cardiovascular Systems*, 911 F.2d 670, 673, 15 USPQ2d 1540, 1542-43 (Fed. Cir. 1990). Summary judgment will not lie if the dispute about a material fact is "genuine," that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The "Written Description" Requirement of §112

The first paragraph of 35 USC 112 requires that

[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(Emphasis added). Application of the "written description" requirement, derived from the portion of §112 emphasized above, is central to resolution of this appeal. The district court, having reviewed this court's decisions on the subject, remarked that "[u]nfortunately, it is not so easy to tell what the law of the Federal Circuit is." 745 F.Supp. at 522, 17 USPQ2d at 1356. Perhaps that is so, and, therefore, before proceeding to the merits, we review the case law development of the "written description" requirement with a view to improving the situation.³

The cases indicate that the "written description" requirement most often comes into play where claims not presented in the application when filed are presented thereafter. Alternatively, patent applicants often seek the benefit of the filing date of an earlier-filed foreign or United States application under 35 USC 119 or 35 USC 120, respectively, for claims of a later-filed application. The question raised by these situa-

tions is most often phrased as whether the application provides "adequate support" for the claim(s) at issue; it has also been analyzed in terms of "new matter" under 35 USC 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the claim(s) corresponding to the count(s) at issue, i.e., whether that party "can make the claim" corresponding to the interference count.

To the uninitiated, it may seem anomalous that the first paragraph of 35 USC 112 has been interpreted as requiring a separate "description of the invention," when the invention is, necessarily, the subject matter defined in the claims under consideration. See *In re Wright*, 866 F.2d 422, 424, 9 USPQ2d 1649, 1851 (Fed. Cir. 1989). One may wonder what purpose a separate "written description" requirement serves, when the second paragraph of §112 expressly requires that the applicant conclude his specification "with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

One explanation is historical: the "written description" requirement was a part of the patent statutes at a time before claims were required. A case in point is *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822), in which the Supreme Court affirmed the circuit court's decision that the plaintiff's patent was "deficient," and that the plaintiff could not recover for infringement thereunder. The patent laws then in effect, namely the Patent Act of 1793, did not require claims, but did require, in its 3d section, that the patent applicant "deliver a written description of his invention, and of the manner of using, or process of compounding, the same, in such full, clear and exact terms, as to distinguish the same from all things before known, and to enable any person skilled in the art or science of which it is a branch, or with which it is most nearly connected, to make, compound and use the same. . . ." *Id.* at 430. In view of this language, the Court concluded that the specification of a patent had two objects, the first of which was "to enable artizans to make and use [the invention]. . . ." *Id.* at 433. The second object of the specification was

to put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be

patented. It is of warning and admonition to the person using the invention of the patentee that the patentee is not to be taken from practicing upon the invention of other persons. . . . *Id.* at 434.

A second, polyclonal inclusion in §112 "written description" requirement "definiter" forth in *Rengo C* F.2d 535, 551, Cir.), cert. denied

[T]here is a . . . the policies un- definiteness re- dards, while c- similar problem Adequate des- guards against by insisting th- in such detail t- determined to original creati- ment shapes th- other than the they receive i- patented device

With respect §112 the severat- tion" provision f- and use") provis- court's precedes- and Patent App- chig, 379 F.2d 9- 1967). Although had presumed t- from was based- ment of §112, id- the court disagre-

[T]he question in the art] wou- er the specifi- pound to him, appellants act- rejection is] b- the requireme- ation shall cc- of the inventio- *Id.* at 995-96, 1- phasis added). T- was one of fact: vey clearly to t- whom it is addre- mation that appe-

³ For additional background, see Rollins, "35 USC 120 — The Description Requirement," 64 J. Pat. Off. Soc'y 656 (1982); Walterscheid, "Insufficient Disclosure Rejections (Part III)," 62 J. Pat. Off. Soc'y 261 (1980).

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patented. It is, therefore, for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Id. at 434.

A second, policy-based rationale for the inclusion in §112 of both the first paragraph "written description" and the second paragraph "definiteness" requirements was set forth in *Rengo Co. v. Molins Mach. Co.*, 657 F.2d 535, 551, 211 USPQ 303, 321 (3d Cir.), cert. denied, 454 U.S. 1055 (1981):

[T]here is a subtle relationship between the policies underlying the description and definiteness requirements, as the two standards, while complementary, approach a similar problem from different directions. Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation. The definiteness requirement shapes the future conduct of persons other than the inventor, by insisting that they receive notice of the scope of the patented device.

With respect to the first paragraph of §112 the severability of its "written description" provision from its enablement ("make and use") provision was recognized by this court's predecessor, the Court of Customs and Patent Appeals, as early as *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967). Although the appellants in that case had presumed that the rejection appealed from was based on the enablement requirement of §112, *id.* at 995, 154 USPQ at 123, the court disagreed:

[T]he question is not whether [one skilled in the art] would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. . . . If [the rejection is] based on section 112, it is on the requirement thereof that "The specification shall contain a written description of the invention * * *." (Emphasis ours.) *Id.* at 995-96, 154 USPQ at 123 (first emphasis added). The issue, as the court saw it, was one of fact: "Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific

compound [claimed]?" *Id.* at 996, 154 USPQ at 123.

In a 1971 case again involving chemical subject matter, the court expressly stated that "it is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention." *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971) (emphasis added). As an example, the court posited the situation "where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described." *Id.* at 1405 n.1, 168 USPQ 593 n.1 (emphases in original). See also *In re Ahlbrecht*, 435 F.2d 908, 911, 168 USPQ 293, 296 (CCPA 1971) (although disclosure of parent application may have enabled production of claimed esters having 2-12 methylene groups, it only described esters having 3-12 methylene groups).

The CCPA also recognized a subtle distinction between a written description adequate to support a claim under §112 and a written description sufficient to anticipate its subject matter under §102(b). The difference between "claim-supporting disclosures" and "claim-anticipating disclosures" was dispositive in *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971), where the court held that a U.S. "grandparent" application did not sufficiently describe the later-claimed invention, but that the appellant's intervening British application, a counterpart to the U.S. application, anticipated the claimed subject matter. As the court pointed out, "the description of a single embodiment of broadly claimed subject matter constitutes a description of the invention for anticipation purposes . . . , whereas the same information in a specification might not alone be enough to provide a description of that invention for purposes of adequate disclosure. . . ." *Id.* at 970, 169 USPQ at 797 (citations omitted).

The purpose and applicability of the "written description" requirement were addressed in *In re Smith and Hubin*, 481 F.2d 910, 178 USPQ 620 (CCPA 1973), where the court stated:

Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application. This concept applies whether

the case factually arises out of an assertion of entitlement to the filing date of a previously filed application under §120... or arises in the interference context wherein the issue is support for a count in the specification of one or more of the parties... or arises in an ex parte case involving a single application, but where the claim at issue was filed subsequent to the filing of the application....

Id. at 914, 178 USPQ at 623-24 (citations omitted).

The CCPA's "written description" cases often stressed the fact-specificity of the issue. See, e.g., *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976) ("The primary consideration is *factual* and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure") (emphasis in original); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close the description must come to comply with §112 must be left to case-by-case development"); *DiLeone*, 438 F.2d at 1405, 168 USPQ at 593 ("What is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed"). The court even went so far as to state:

[I]t should be readily apparent from recent decisions of this court involving the question of compliance with the description requirement of §112 that each case must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited.

In re Driscoll, 562 F.2d 1245, 1250, 195 USPQ 434, 438 (CCPA 1977).

Since its inception, the Court of Appeals for the Federal Circuit has frequently addressed the "written description" requirement of §112.⁴ A fairly uniform standard

⁴ See, *Chester v. Miller*, 906 F.2d 1574, 15 USPQ2d 1333 (Fed. Cir. 1990) (parent application's disclosure of chemical species constituted 102(b) prior art against continuation-in-part (c-i-p) application on appeal, but did not provide sufficient written description to support c-i-p's claims to encompassing genus); *In re Gostelli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (foreign priority application's disclosure of chemical subgenus was insufficient written description to support genus claims of corresponding U.S. application); *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989) (application in "clear compliance" with §112 "written description" requirement with respect to claim limitation that microcapsules were "not permanently fixed"); *Utter v. Hiraga*, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) (holding generic interference count to scroll-com-

pressor supported by written description of foreign priority application, the court stated, "A specification may, within the meaning of 35 U.S.C. §112 ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses"); *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 5 USPQ2d 1194 a (Fed. Cir. 1987) (parent application's lack of express disclosure of inherent "equiaxed microstructure" property did not deprive c-i-p's claims to a sintered ceramic body having said property of the benefit of parent's filing date), *cert. denied*, 486 U.S. 1008 (1988); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 227 USPQ 177 (Fed. Cir. 1985) (parent application's disclosure provided adequate written description support for certain claim limitations respecting protein content, temperature, and moisture content, but not others); *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984) (broadly worded title, general description of drawing, and objects of invention of parent patent application did not adequately support reissue application claims directed to genus of indicating mechanisms for dictating machines), *cert. denied*, 469 U.S. 1209 (1985); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983) (claims to method of redeeming merchandise coupons, comprising step of providing an audit of coupon traffic, were not supported by specification of parent application).

There appears to be some confusion in our decisions concerning the extent to which the "written description" requirement is separate and distinct from the enablement requirement. For example, in *In re Wilder*, 736

F.2d 1516, 1520 Cir. 1984), *cer* (1985), we flatly requirement is f is separate from of that provision we said, "The p scription require paragraph] is t fulfill the enab quirements may they are intervy *Kyocera Int'l, I* USPQ2d 1194, *denied*, 486 U.S. description must needed to enable and use the claim

[2] To the ext with *Wilder*, w three-judge pane turn prior preced *Elec. Co. v. Unit* n.6, 2 USPQ2d 1987), *cert. den* This court in *Wi* it) clearly recog firm, that 35 U requires a "writt tion" which is se enablement requ "written descript than to merely use"; the applic reasonable clarit that, as of the fi was in possession tion is, for purpo tion" inquiry, w

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For example, "[t]here is no st an applicant's re under 35 U.S.C. design applicatio are met." *Kangador, Inc.*, 778 F. 32, 33 (Fed. Cir. er the applicant's tic shoes was in fa of his earlier des solved in *Kanga*.

settled and long-established Patent Office practice. . . . Consider, for one thing, that the sole disclosure in a design patent application is by means of a drawing. . . . For another thing, consider that the only informative and significant disclosure in many electrical and chemical patents is by means of circuit diagrams or graphic formulae, constituting "drawings" in the case. . . .

. . . The practical, legitimate enquiry in each case of this kind is what the drawing in fact discloses to one skilled in the art.

. . . The issue here is whether there is supporting "disclosure" and it does not seem, under established procedure of long standing, approved by this court, to be of any legal significance whether the disclosure is found in the specification or in the drawings so long as it is there.

Id. at 955-56, 133 USPQ at 541-42.

Employing a "new matter" analysis, the court in *In re Heinle*, 342 F.2d 1001, 145 USPQ 131 (CCPA 1965) reversed a PTO rejection of the applicant's claims to a "toilet paper core" as "including subject matter having no clear basis in the application as filed." *Id.* at 1003, 145 USPQ at 133. The claim limitation said to be without support required that the width of the apertures in the core be "approximately one-fourth of the circumference of said core." *Id.* at 1007, 145 USPQ at 136. Having reviewed the application drawings relied upon for support, the court stated:

it seems to us that [the drawings] conform to the one-fourth circumference limitation almost exactly. But the claim requires only an approximation. Since we believe an amendment to the specification to state that one-fourth of the circumference is the aperture width would not violate the rule against "new matter," we feel that supporting disclosure exists. The rejection is therefore in error.

Id.

[3] These cases support our holding that, under proper circumstances, drawings alone may provide a "written description" of an invention as required by §112. Whether the drawings are those of a design application or a utility application is not determinative, although in most cases the latter are much more detailed. In the instant case, however, the design drawings are substantially identical to the utility application drawings.

Although we join with the district court in concluding that drawings may suffice to satisfy the "written description" requirement of §112, we can not agree with the legal stand-

ard that the court imposed for "written description" compliance, nor with the court's conclusion that no genuine issues of material fact were in dispute.

With respect to the former, the district court stated that although the '081 design drawings in question "allowed practice" [i.e., enabled], they did not necessarily

show what the invention is, when "the invention" could be a subset or a superset of the features shown. Is the invention the semi-circular lumens? The conical tip? The ratio at which the tip tapers? The shape, size, and placement of the inlets and outlets? You can measure all of these things from the diagrams in serial '081 and so can practice the device, but you cannot tell, because serial '081 does not say, what combination of these things is "the invention", and what range of variation is allowed without exceeding the scope of the claims. To show one example of an invention, even a working model, is not to describe what is novel or important. 745 F.Supp. at 522, 17 USPQ2d at 1356.

[4] We find the district court's concern with "what the invention is" misplaced, and its requirement that the '081 drawings "describe what is novel or important" legal error. There is "no legally recognizable or protected 'essential' element, 'gist' or 'heart' of the invention in a combination patent." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 [128 USPQ 354] (1961). "The invention" is defined by the claims on appeal. The instant claims do not recite *only* a pair of semi-circular lumens, or a conical tip, or a ratio at which the tip tapers, or the shape, size, and placement of the inlets and outlets; they claim a *double lumen catheter* having a *combination* of those features. That combination invention is what the '081 drawings show. As the district court itself recognized, "what Mahurkar eventually patented is exactly what the pictures in serial '081 show." 745 F.Supp. at 523, 17 USPQ2d at 1357.

We find the "range of variation" question, much emphasized by the parties, more troublesome. The district court stated that "although Mahurkar's patents use the same diagrams, [the claims] contain limitations that did not follow ineluctably [i.e., inevitably] from the diagrams." *Id.* at 524, 17 USPQ2d at 1357. As an example, the court stated (presumably with respect to independent claims 1 and 7 of the '329 patent) that the utility patents claim a return lumen that is "substantially greater than one-half but substantially less than a full diameter" after it makes the transition from semi-circular to circular cross-section, and the

drawings of serial '081. But until the utility patents established nothing establishing that matter that they claim anything other than the diagrams.

Id. at 523, 17 USPQ2d at 1357. The court argues that one of the purposes of looking at the '081 drawings is to derive the claimed invention.

The declaration of invalidity submitted by Mahurkar concerns Dr. Ash's expertise in nephrology (the study of kidney diseases) and chairmanship of the National Kidney Foundation (which develops and manufactures medical devices including catheters). Dr. Ash's skill in the art of catheter manufacture, studying serial '081 application in connection with the '081 drawings, is understood from their testimony that they must have a diameter of 0.5 mm, as evidenced by independent claim 1 of the '081 patent. Dr. Ash explains that a return lumen (longer lumen) of half that of the two lumens would produce too great a pressure drop, a return lumen of diameter less than that of the two lumens would result in too great a pressure drop. Dr. Ash's many years of experience with catheters would lead him to such an arrangement.

Although the district court's reasoning "logical," it is not the issue issued to Mahurkar, which is closer to 1.0 (U.S. 1.0 mm) and exactly 0.5 (U.S. 0.5 mm) (272,651). If these calculations are correct, the district court's conclusion that serial '081 necessarily discloses a return lumen of 0.5 mm (F.Supp. at 523, 17 USPQ2d at 1357).

[5] The district court's conclusion that Mahurkar's other patents disclose a return lumen of 0.5 mm (F.Supp. at 523, 17 USPQ2d at 1357) is not the issue at hand. Application of §112, first paragraph, requires that the filing date. *United States v. American*

'Higher pressure drop' smaller cross-sectional area. Mahurkar's opening brief applies well-known principles (i.e., the work of Poiseuille) to calculate that the diameter of the return lumen would have to be times the diameter of the main lumen in order to achieve proper pressure drop. The 0.66 ratio is the claim limitation.

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drawings of serial '081 fall in this range. But until the utility application was filed, nothing established that they had to — for that matter that the utility patent would claim anything other than the *precise* ratio in the diagrams. . . .

Id. at 523, 17 USPQ2d at 1357. Mahurkar argues that one of ordinary skill in this art, looking at the '081 drawings, would be able to derive the claimed range.

The declaration of Dr. Stephen Ash, submitted by Mahurkar, is directed to these concerns. Dr. Ash, a physician specializing in nephrology (the study of the kidney and its diseases) and chairman of a corporation that develops and manufactures biomedical devices including catheters, explains why one of skill in the art of catheter design and manufacture, studying the drawings of the '081 application in early 1982, would have understood from them that the return lumen must have a diameter within the range recited by independent claims 1 and 7 of the '329 patent. Dr. Ash explains in detail that a return (longer) lumen of diameter less than half that of the two lumens combined would produce too great a pressure increase, while a return lumen of diameter equal or larger than that of the two lumens combined would result in too great a pressure drop.⁷ "Ordinary experience with the flow of blood in catheters would lead directly away from any such arrangement," Ash states.

Although the district court found this reasoning "logical," it noted that later patents issued to Mahurkar disclose diameter ratios closer to 1.0 (U.S. Patent No. 4,584,968) and exactly 0.5 (U.S. Des. Patent No. 272,651). If these other ratios were desirable, the district court queried, "how does serial '081 necessarily exclude the[m]?" 745 F.Supp. at 523, 17 USPQ2d at 1357.

[5] The district court erred in taking Mahurkar's other patents into account. Mahurkar's *later* patenting of inventions involving different range limitations is irrelevant to the issue at hand. Application sufficiency under §112, first paragraph, must be judged as of the filing date. *United States Steel Corp. v.*

⁷ Higher pressure drops are associated with smaller cross-sectional areas for fluid flow. Mahurkar's opening brief to this court states that by applying well-known principles of fluid mechanics (i.e., the work of Poiseuille and Hagen), it can be calculated that the diameter of the circular (return) lumen would have to be in the range of 0.66 times the diameter of the two lumens combined in order to achieve proper blood flow at equal pressure drop. The 0.66 ratio falls within the noted claim limitation.

Phillips Petroleum Co., 865 F.2d 1247, 1251, 9 USPQ2d 1461, 1464 (Fed. Cir. 1989).

[6] The court further erred in applying a legal standard that essentially required the drawings of the '081 design application to *necessarily exclude* all diameters other than those within the claimed range. We question whether any drawing could ever do so. At least with respect to independent claims 1 and 7 of the '329 patent and claims depending therefrom, the proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that Mahurkar had in fact invented the catheter recited in those claims, having (among several other limitations) a return lumen diameter substantially less than 1.0 but substantially greater than 0.5 times the diameter of the combined lumens. Consideration of what the drawings conveyed to persons of ordinary skill is essential. *See Ralston Purina*, 772 F.2d at 1575, 227 USPQ at 179 (ranges found in applicant's claims need not correspond *exactly* to those disclosed in parent application; issue is whether one skilled in the art could derive the claimed ranges from parent's disclosure).

Mahurkar submitted the declaration of Dr. Ash on this point; Vas-Cath submitted no technical evidence to refute Ash's conclusions. Although the district court considered Dr. Ash's declaration, we believe its import was improperly disregarded when viewed through the court's erroneous interpretation of the law.⁸ We hold that the Ash declaration and Vas-Cath's non-refutation thereof, without more, gave rise to a genuine issue of material fact inappropriate for summary disposition. *See Hesston Corp. v. Sloop*, 1988 U.S. Dist. LEXIS 1573, *13 (D. Kansas) (summary judgment on §112 "written description" issue inappropriate where resolution of what parent disclosure conveyed to those skilled in the art may require examination of experts, demonstrations and exhibits).

⁸ The following colloquy at oral argument before the district court supports our view:

Counsel for Mahurkar: "So the only evidence that we have on this subject from people of ordinary skill in the art is that the drawings do communicate these range limitations, and given the procedural posture of this case, the Court has to accept that evidence. . . ."

District Court: * * * "And if you could have written a large number of things that were different from what was actually filed in 1984, then the diagram isn't enough."

And that seems to me something that can't be resolved by ogling the Ash declaration. It's really a pure question of law."

Mahurkar urges that at least some of the remaining claims do not contain the range limitations discussed by the district court, and that the presence of range limitations was not a proper basis for invalidating those remaining claims. For example, claim 8 of the '141 patent requires, *inter alia*, a smooth conical tapered tip and "the portion of said tube between said second opening and said conical tapered tip *being larger than* said first lumen in the transverse direction normal to the plane of said septum." Vas-Vath counters that claim 8 of the '141 patent is just as much a "range" claim as claims 1 and 7 of the '329 patent, albeit one having only a lower limit and no upper limit.

Absent any separate discussion of these remaining claims in the district court's opinion, we assume that the court applied to them the same erroneous legal standard. Summary judgment was therefore inappropriate as to the remaining claims. Additionally, the possibility that the '081 drawings may provide an adequate §112 "written description" of the subject matter of some of the claims but not others should have been considered. *See, e.g., In re Borkowski*, 422 F.2d 904, 909 n.4, 164 USPQ 642, 646 n.4 (CCPA 1970) (on review of §112 non-enablement rejection: "A disclosure may, of course, be insufficient to support one claim but sufficient to support another.") On remand, the district court should *separately* analyze whether the "written description" requirement has been met as to the subject matter of *each* claim of the '141 and '329 patents.

CONCLUSION

The district court's grant of summary judgment, holding all claims of the '329 and '141 patents invalid under 35 USC 102(b), is hereby reversed as to all claims, and the case remanded for further proceedings consistent herewith.

COSTS

Each party to bear its own costs.
REVERSED and REMANDED

APPENDIX

Independent Claims of the '329 Patent:

1. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicat-

ing with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, wherein said second cylindrical portion has a diameter substantially greater than one-half but substantially less than a full diameter of said first cylindrical portion.

7. A double lumen catheter having an elongated tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, said second cylindrical portion having a diameter substantially greater than one-half but substantially less than a full diameter of said first cylindrical portion, said divider in said first cylindrical portion being planar, the lumens being "D" shaped in cross-section in said first cylindrical portion, the elongated tube being provided with a plurality of holes in the region of the conical tapered tip, and said first cylindrical portion of the elongated tube smoothly merging with said second cylindrical portion of the elongated tube.

Independent Claims of the '141 Patent:

1. A double lumen catheter having an elongated tube with a proximal first cylindri-

cal portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

said elongated tube having at its distal end a smooth conical tapered tip that smoothly merges with a second cylindrical portion of said elongated tube, and said second cylindrical portion enclosing the first lumen from the conical tapered tip to approximately the location of said second opening, wherein said [sic] portion has a diameter substantially less than a full diameter of said first cylindrical portion, the elongated tube being provided with a plurality of holes in the region of the conical tapered tip, and said first cylindrical portion of the elongated tube smoothly merging with said second cylindrical portion of the elongated tube.

7. A double lumen catheter having an elongated cylindrical tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

8. A double lumen catheter having an elongated cylindrical tube with a proximal first cylindrical portion enclosing first and second lumens separated by an internal divider, the proximal end of said elongated tube connecting to two separate connecting tubes communicating with the respective first and second lumens for the injection and removal of fluid, the first lumen extending from the proximal end of said elongated tube to a first opening at the distal end of said elongated tube, and the second lumen extending from the proximal end of said elongated tube to a second opening at approximately the distal end of said first cylindrical portion, wherein the improvement comprises:

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